The 510(k) Process
"What You Need to Know"

FDA Small Business
Regulatory Education for Industry (REdI)
Bethesda, MD
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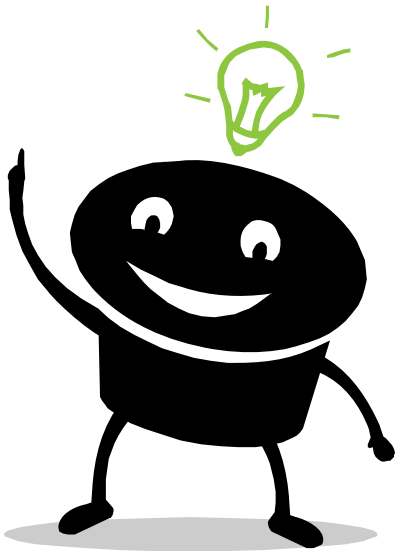
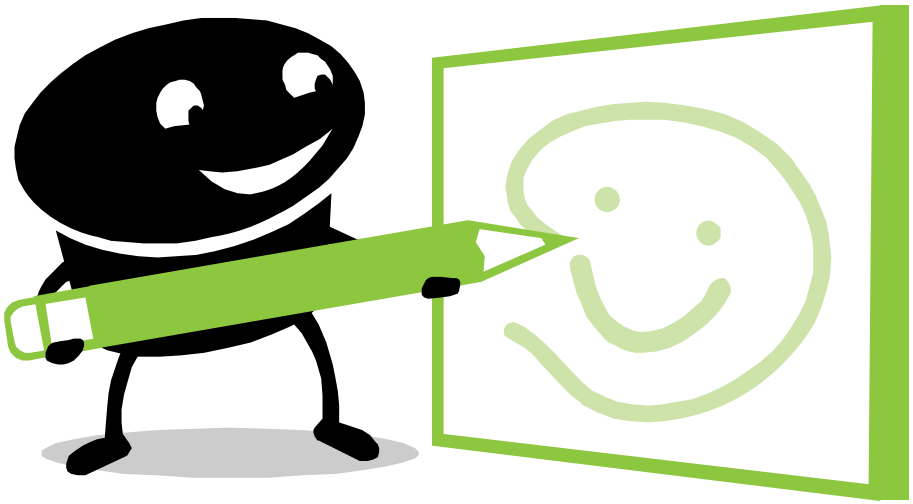
A 510(k) notification is one of the major processes in device marketing…



…but how?

When I say 510(k), you may feel like this…

Hopefully, by the end of this presentation, you will feel more like this…



Presentation Outline

- Device Classification As It Relates to 510(k)s
- Overview of 510(k) Program
- A 510(k) Submission
- Submission to FDA and User Fees
- 510(k) Review Times and FDA Actions
- 510(k) Decisions
- Top 510(k) Inquiries from Industry
- References and Resources
- Discussion

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Medical Device Classification

- Class I = Low Risk Devices
- **Class II = Moderate Risk Devices**
  - ***Most, not all, Class II devices require a premarket notification or 510(k).***
- Class III = High Risk Devices

**NOTE: All classes are subject to general controls such as labeling and Good Manufacturing Practices (unless exempt).*

Product Codes

- Three letter codes.
- Used by FDA to identify and track similar medical devices.
- Used by applicants to search for predicate devices.
- Found on all 510(k) clearance letters.

- References:
  - Draft Guidance Medical Device Classification Product Codes (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm285317.htm)
  - Product Classification Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm)

Product Classification Example

Device	Ventilator, Continuous, Facility Use
Regulation Description	Continuous ventilator.
Regulation Medical Specialty	Anesthesiology
Review Panel	Anesthesiology
Product Code	CBK
Submission Type	510(k)
Regulation Number	868.5895
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Recognized Consensus Standards

- ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets
- IEC 60601-2-12:(2001-10): Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators

Guidance Document

- Draft Reviewer Guidance for Ventilators PDF

Third Party Review	Not Third Party Eligible

What do you do if…

You cannot determine the device classification?

Consider the **513(g) Program**

513(g) Request for Information

- Section 513(g) of the FD&C Act (21 U.S.C. 360c(g)) provides a means for obtaining the agency's views about product classification and the regulatory requirements that may be applicable to your particular device.

- "Typical" 513(g) Inquiries:
  - Determine whether a product is subject to FDA regulations.
  - Determine whether a device is exempt from the 510(k) requirements of the Act.
  - Determine whether a 510(k) is needed for a modification to one's device.
  - Determine the least burdensome regulatory pathway for a device, which introduces a new technology or a new intended use.

513(g) Important Notes

* There is a 513(g) User Fee. FY2014 it will be $3,490 ($1,745 for a small business).

* FDA responses to requests for information about the regulatory requirements applicable to a particular device DO NOT constitute FDA clearance or approval for distribution of that particular device in the U.S.

- References:
  - Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209841.htm)
  - Guidance for Industry and Food and Drug Administration Staff - User Fees for 513(g) Requests for Information (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209852.htm)
  - Medical Device User Fee Rates for Fiscal Year 2014: http://www.gpo.gov/fdsys/pkg/FR-2013-08-02/pdf/2013-18623.pdf)

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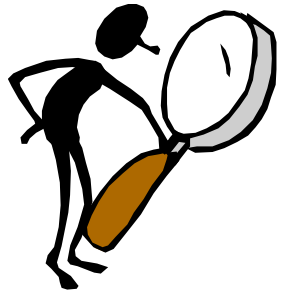
What is a 510(k) Vs. What is Not a 510(k)

- Premarket Notification
- Section 510(k) of Federal FD&C Act
- 21 CFR 807 Subpart E
- It is a marketing clearance application
- 510(k)s are “cleared”
- Allows FDA to determine Substantial Equivalence (SE)

- A Form
- Establishment Registration
- Device Listing
- Premarket Approval (PMA)

What is a Predicate Device?

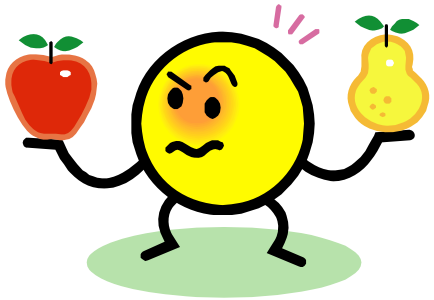


- A legally marketed device, previously cleared through the 510(k) process *mainly*, that is used for comparison to a new device for the purpose of determining substantial equivalence (21 CFR 807.92(a)(3)).

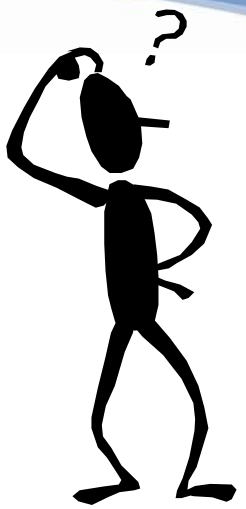
- Reference:
  - How To Find A Predicate Device (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm)

What is Substantial Equivalence (SE)?

- Demonstration that a new device, as compared to a predicate device, has…
  - the same intended use,
  - the same technological characteristics, or
  - differences that do not raise different questions regarding safety and effectiveness.

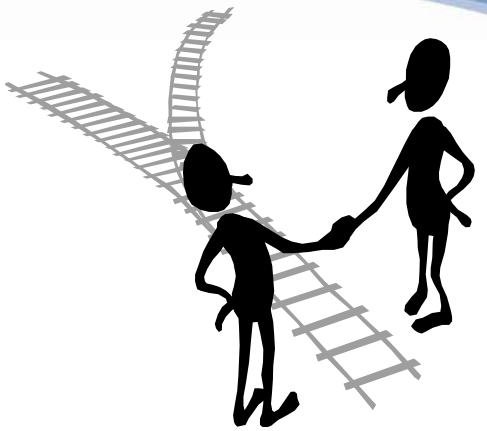


When is a 510(k) Required?



- Introducing a device to the market for the first time.
- Changing the indications for use of a previously cleared device.
- Making significant modification(s) to a previously cleared device.

510(k) Exempt Devices



- Devices exempt by statute or by regulation from 510(k)

- Note: Limitations of device exemptions are covered under 21 CFR XXX.9

- Reference:
  - When a 510(k) is Not Required (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm)

Types of 510(k) Submissions

Traditional 510(k)

Abbreviated 510(k)

Special 510(k)

NOTE: The Abbreviated 510(k) and Special 510(k) methods can only be used if certain criteria are met. **The Traditional 510(k) method can be used under any circumstance.**

•Reference:

- How to Prepare A Traditional 510(k) (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134572.htm)

Abbreviated 510(k)

•Relies on the use of guidance documents, special controls, and recognized standards.

•Required elements (21 CFR 807.87).

•Under certain conditions, sponsors may not need to submit test data in an abbreviated 510(k).

•Reference: How to Prepare An Abbreviated 510(k) (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134574.htm)

Special 510(k)

•Device modification to manufacturer's own legally marketed device.

•Modification does NOT affect the intended use or fundamental scientific technology.

•Required elements (21 CFR 807.87).

•No data is evaluated by FDA.

•Reference: How to Prepare A Special 510(k) (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134573.htm)

What do you do if…

You have a low or moderate risk device with no identifiable predicate devices?

De Novo

De Novo

- Also known as “Evaluation of Automatic Class III Designation” or "risk-based" classification.

- The De Novo process provides a possible route to market low risk device types that have been classified as Class III devices because there are no legally marketed identifiable predicate devices.

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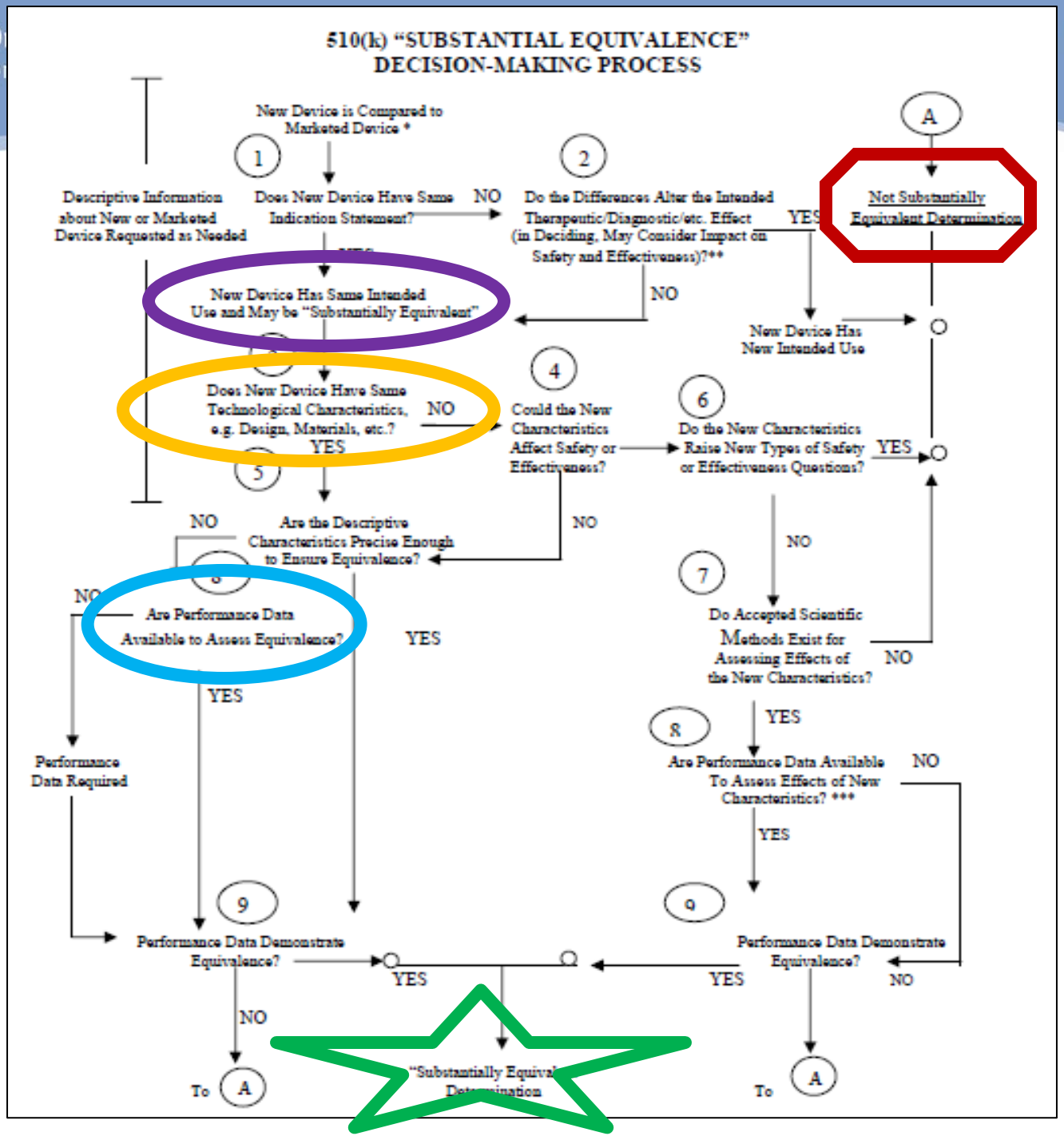
510(k) Decision-Making Flow Chart



Establishing Substantial Equivalence

Three Important Questions

1. Does the new device have the same indications for use statement?

2. Does the new device have the same technological characteristics?

3. Are performance data available to assess equivalence?

- Reference:
  - 510(k) Substantial Equivalence Decision-Making Process (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM081395.pdf)

A 510(k) Submission

- Administrative Requirements
- Critical Elements

Administrative Requirements

- **Per 21 CFR 807.87**
- Medical Device User Fee Cover Sheet (Form FDA 3601)
- CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)
- 510(k) Cover Letter
- Truthful and Accuracy Statement
- Financial Certification or Disclosure Statement
- eCopy
- Etc.
- Reference:
  - 510(k) Screening Checklist (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm071360.htm)

Pre-Sub for a 510(k)*

- *DRAFT Guidance: The Pre-Submission Program and Meetings with FDA Staff.
- Obtain FDA feedback prior to submission of your 510(k).
- Submit a formal written request to the FDA.
- Request either a formal written response, meeting, or teleconference to address their concerns, questions, etc.
- Subject to eCopy requirements.
- Reference: Draft Guidance [Pre-Sub for a 510(k) - See Appendix C] (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm)

Critical Elements

- Necessary to demonstrate safety and effectiveness:
  - Performance Testing
  - Biocompatibility
  - Electrical Safety/EMC
  - Software
  - Sterility

"Key 4"

When thinking about the critical elements, remember the following:

1) Safety
2) Effectiveness
3) FDA Guidance Documents
4) FDA Recognized Consensus Standards

FDA Guidance Documents

- Represents FDA's current thinking on a topic.
- May be device specific or general.
- Does not create or confer any rights for or on any person and does not operate to bind FDA or the public.
- Alternative approaches may be used if the approach satisfies the requirements of the applicable statutes and regulations.

- Reference:
  - FDA Guidance Document Database (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

FDA Recognized Consensus Standards

- Voluntary program.
- Used to simplify and streamline the 510(k) review process.
- Sponsors can only declare conformance to FDA recognized consensus standards.
- Must document extent of conformance in 510(k) application.

- References:
  - Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm)
  - Frequently Asked Questions on Recognition of Consensus Standards (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm074973.htm)
  - Recognized Consensus Standards Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm)
  - Standards Data Form for 510(k)s (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf)

Recap: Product Classification Example

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Guidance Document

- Draft Reviewer Guidance for Ventilators PDF

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Performance Testing

- Bench, Animal, or Clinical.
- Necessary performance tests depend on the complexity of the device and its intended use and indications.
- Consider FDA Guidance Documents.
- Consider comparative testing to demonstrate substantial equivalence.
- Include: test methods, acceptance criteria and test results for review.

Biocompatibility

- To determine the potential toxicity resulting from contact of the component materials of the device with the body.
- Appropriate tests are determined based on the nature, degree, frequency and duration of its exposure to the body.
- The final product should be tested (this includes after sterilization, if applicable).
- Include: test methods, acceptance criteria and test results for review.

- **References:**
  - Use of ISO 10993 "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm)
  - 510(k) Memorandum - #G95-1 Table 1 Initial Evaluation Tests for Consideration (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080742.htm)
  - Special Considerations – Biocompatibility (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134578.htm)
  - Draft Guidance (April 23, 2013) : Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM348890.pdf)

Electrical Safety and EMC

- Electrical Safety (e.g. electric shock, burns, or electrical interference, leakage current, etc.) and Electromagnetic Compatibility (EMC).

- Recognized Consensus Standards IEC 60601-1-2 Medical Electrical Equipment or an equivalent method.

- References:
  - Electromagnetic Compatibility (EMC) (http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/default.htm)
  - Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077210.htm)
  - Wireless Medical Devices (http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/WirelessMedicalDevices/default.htm)

Software

- Software development and validation should be based on the level of risk of the software.
- The extent of documentation that we recommend you submit for your software device is proportional to the Level of Concern associated with the device.
- Level of Concern (Major, Moderate or Minor).

- References:
  - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm)
  - Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073779.pdf)
  - Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm)

Sterility

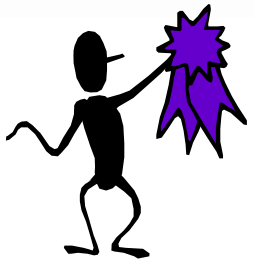
- Sterilization is defined as a validated process used to render a product free of all forms of viable microorganisms.

- References:
  - Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm
  - Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile (Intended to supersede K90-1): http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm109884.htm
  - Liquid Chemical Sterilization: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/ucm208018.htm
  - Guidance for Industry and FDA Reviewers: Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073773.htm

What to Include in 510(k) Submission for a Sterile, Single Use Device

1. Sterilant
   a) Sterilization method (e.g. Steam, EtO, Radiation)
   b) Dose for radiation (e.g. 25-50 kGy)
   c) Sterilant residuals remaining on the device
2. Validation Method for Sterilization
3. Sterility Assurance Level (SAL) (e.g. 10^{-6})
4. If labeled “Pyrogen Free” provide description of method (e.g. LAL (Limulus Amebocyte Lysate test))
5. Packaging Description

Key Considerations



- Information is complete and organized.
  - Include a table of contents.
  - Use tabs and paginate properly.
  - Utilize tables and graphs appropriately and effectively.
  - Use visual aids whenever possible.
- Clearly identify basic 510(k) requirements (e.g. 510(k) Summary, Indications for Use Form, etc.).
- Be consistent throughout the submission.
- Understand and follow the 510(k) decision-making flowchart.
- Follow current applicable guidance documents and device specific checklists.
- Keep informed about regulatory changes (e.g. proposed/final regulations).

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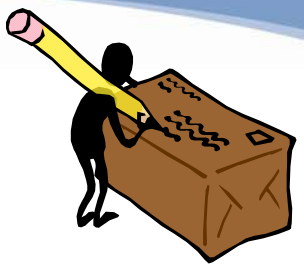

Submission to FDA

- You must submit **two copies** of your 510(k).
- One of your two copies must be submitted in an electronic format.
- FDA does NOT return the 510(k) submission after review.
- Address:

  Food and Drug Administration
  Center for Devices and Radiological Health
  Document Control Center - WO66-G609
  10903 New Hampshire Avenue
  Silver Spring, Maryland 20993-0002

- Reference:
  - Addresses for Submissions (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm135103.htm)

eCopy Program

- Food and Drug Administration Safety and Innovation Act (FDASIA), requires the submission of eCopies.
- As of Jan. 1, 2013, FDA will only place a pre-market submission under review if it has an eCopy that has been validated by FDA's eCopy loading system.
- An eCopy is defined as an exact duplicate of the paper submission, created and submitted on a compact disc (CD), digital video disc (DVD), or a flash drive.
- An eCopy is accompanied by a paper copy of the signed cover letter and the complete paper submission.
- Questions regarding eCopy requirements or responses to eCopy holds should be sent to CDRH-eCopyinfo@fda.hhs.gov.

- Reference:
  - Guidance eCopy Program for Medical Device Submissions (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf)

Premarket Notification [510(k)] Review Fees

FY2014 Device Review User Fees (U.S. Dollars)		
Submission	Standard Fee	Small Business Fee
510(k)	**$5,170**	**$2,585**

References:
•Premarket Notification [510(k)] Review Fees (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134566.htm)
•Guidance FY 2014 Medical Device User Fee Small Business Qualification and Certification (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM314389.pdf)

Refuse to Accept (RTA) Policy for 510(k)s

- Is the 510(k) submission administratively complete for substantive review?
- Early Review – 15 calendar days from receipt.
- Necessary elements and content of a complete 510(k) submission (Refer to RTA Checklist in Guidance).
- FDA clock begins on the date of receipt when the 510(k) is "accepted for review."

- Reference:
  - Final Guidance Refuse to Accept Policy for 510(k)s (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf)

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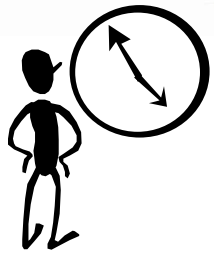
FDA Review Times



510(k) Submission Type	FDA Review Days
Traditional and Abbreviated	90
Special	30

- Reference:
  - MDUFA III Performance Goals (http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf)

Overview of 510(k) Review Process

1. Applicant pays 510(k) user fee.
2. User fee payment is verified.
3. 510(k) submission log-in at Document Control Center.
4. Validation of eCopy.
5. Administrative review (RTA Policy).
6. Division acceptance within the Office of Device Evaluation (ODE) or Office of In Vitro Diagnostics and Radiological Health (OIR).
7. Assignment to premarket reviewer or review group.
8. FDA review.
9. *(Additional Information (AI) Requests and/or Interactive Review).*
10. FDA issue decision letter.
11. SE decision letter made public within 30 Days.

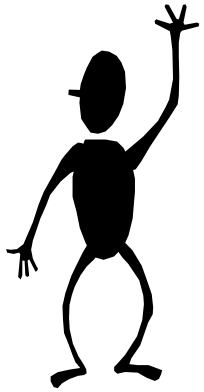
FDA Review Teams

May include:

- Lead Reviewer (e.g. chemical, mechanical, biomedical or electrical engineer, chemist, biologist, nurse consultant)
- Clinical Reviewer
- Statistician
- Specialty Reviewers (e.g. software, biocompatibility, microbiology, chemistry, toxicology, etc.)
- Project Manager
  - Assists with inter-center consults
  - Sets up meetings and teleconferences

Requests for Additional Information (AI)

- **Why is additional information requested?**
  - Testing data required to demonstrate equivalence.
  - Reviewer has questions regarding labeling, wording, etc.



- **How is additional information requested?**
  - Reviewer request by telephone, email or letter.
  - AI responses are subject to eCopy requirements.

- **How does this affect the submission review times?**
  - Clock stops when a submission is officially placed on hold.
  - AI response must be submitted to the Document Control Center.
  - Applicants will be given a maximum of 180 days from the date of the additional information request to provide a complete response.
  - Interactive review requests do not stop the clock.

Interactive Review

- Informal interaction between FDA and applicants during the review of 510(k) submissions.
- Prevent unnecessary delays.
- Reduce the overall time to market.
- Ensure that FDA's concerns are clearly communicated.
- Minimize the number of review cycles.
- Ensure timely responses from applicants.
- *NOTE: Interactive Review correspondence is not subject to eCopy requirements unless submitted through the Document Control Center.

- Reference:
  - Guidance - Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm)
  - Types of Communication During the Review of Medical Device Submissions - Draft Guidance for Industry and Food and Drug Administration Staff (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm341918.htm)

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- 510(k) Review Times and FDA Actions
- **510(k) Decisions**
- Top 510(k) Inquiries from Industry
- References and Resources
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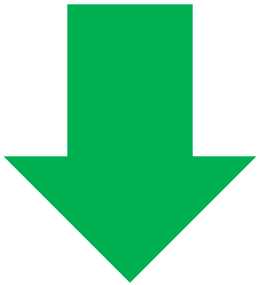
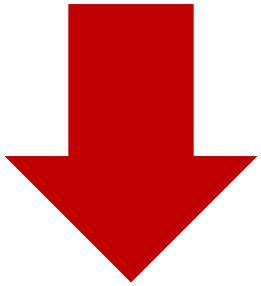
510(k) Decisions

- **SE Decision**



Device To Market.

- **NSE Decision**



Resubmit another 510(k) with new data, PMA, de novo, Humanitarian Device Exemption (HDE) or reclassification petition.

Why might you receive a NSE Decision?

1. There is no predicate device.

2. Your device has a NEW intended use.

3. Your device has different technological characteristics compared to the predicate device and raises new types of questions regarding safety and effectiveness.

4. You did not demonstrate that your device is at least as safe and effective as the predicate.

What Happens After a Device is Cleared?

- The following are posted on the FDA's online public database:
  - SE Letter
  - Indications for Use Form
  - 510(k) Summary (if provided instead of 510(k) Statement)

*NOTE: For 510(k) Statements, applicants must make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142664.htm)

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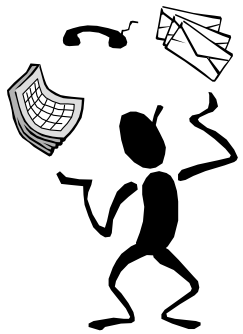
Top 4 - 510(k) Inquiries from Industry

1. Changes to an Existing Device
2. Bundling
3. Add to File
4. Transfer 510(k) Ownership

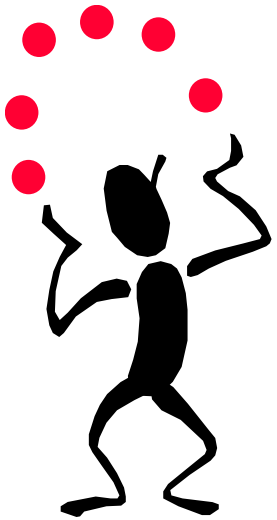


Changes to an Existing Device

- Examples of modifications that may require a 510(k) submission include, but are not limited to, the following:
  - Sterilization method
  - Structural material
  - Manufacturing method
  - Operating parameters or conditions for use
  - Patient or user safety features
  - Sterile barrier packaging material
  - Stability or expiration claims
  - Design

- References:
  - Is a new 510(k) required for a modification to the device? (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070202.htm)
  - Deciding When to Submit a 510(k) for Change to an Existing Device Guidance (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm)

Bundling



- The inclusion of multiple devices or multiple indications for use for a device in a single premarket submission.

- In determining whether a bundled submission can be reviewed during the course of **one review**, FDA may consider whether: (i) the supporting data are similar; (ii) primarily one review division/group will be involved; and (iii) the devices or indications for use are similar.

- Reference:
  - Guidance "Bundling Multiple Devices or Multiple Indications in a Single Submission" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089731.htm)

Add to File

- Add to Files are voluntary. However, a company must note changes in their own files.
- Describe in detail what additions, changes, or modifications you intend to make that do not require a new 510(k).
- Be sure to reference your 510(k) number and clearly indicate that your submission is an Add to file.
- Add to Files should be sent to the following address:

  U.S. Food and Drug Administration
  Center for Devices and Radiological Health
  Document Control Center – WO66-G609
  10903 New Hampshire Avenue
  Silver Spring, MD 20993-0002

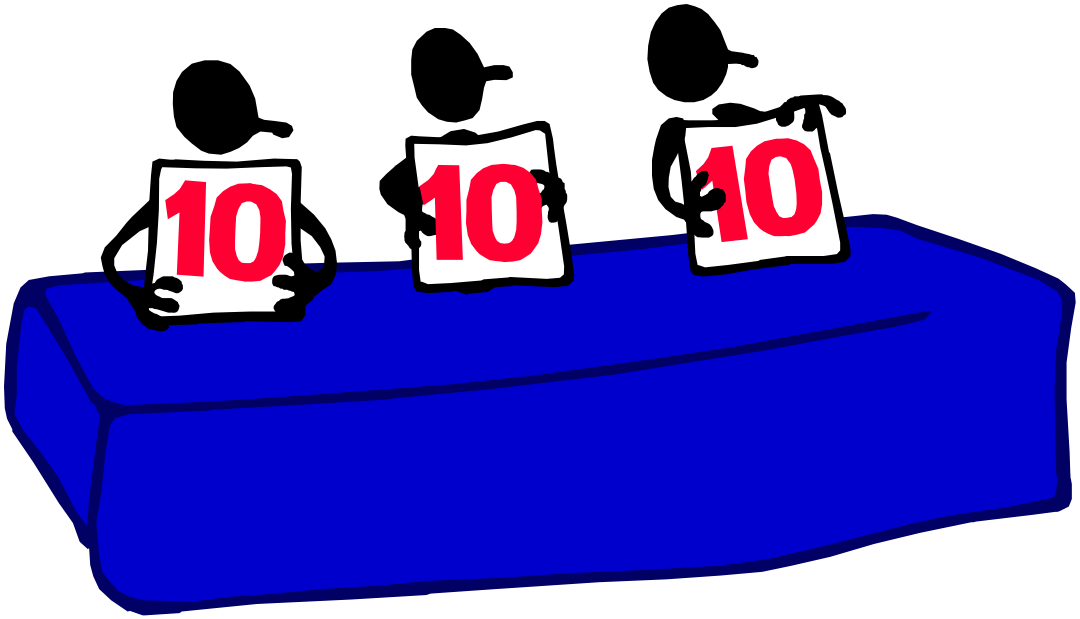
- **NOTE: Add to Files are considered amendments to 510(k)s - they are subject to eCopy requirements for a 510(k).*

Transfer of 510(k) Ownership

- A cleared 510(k) cleared may be bought, sold, or transferred from one owner to another. FDA is not involved in the financial transaction.

- **Remember:**
  - The new owner should maintain documentation of transfer and all appropriate device records.
  - The new owner must manufacturer the device according to 510(k) cleared specifications.
  - The new and previous owners must update device registration and listing.
  - A copy of the transfer should accompany all shipments to the U.S.
  - No new 510(k) clearance letter will be issued.
  - It is voluntary to inform FDA of a transfer. If a company chooses to then they may submit an Add to File, citing 510(k) number.

Your Future 510(k) Submission



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Additional 510(k) References

- Device Advice: Comprehensive Regulatory Assistance: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm
- How to Market Your Device: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm
- Premarket Submissions: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/default.htm
- Premarket Notification (510k): http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm
- Content of a 510(k) (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm)
- Guidance Format for Traditional and Abbreviated 510(k)s (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm)
- 510(k) Forms (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070202.htm)

Additional 510(k) References

- Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm
- Draft Guidance: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm282958.htm
- 510(k) "Substantial Equivalence" Decision Making Process: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134783.htm
- Premarket Notification [510(k)] Review Fees: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134566.htm
- Guidance for Industry and Food and Drug Administration Staff - User Fees and Refunds for Premarket Notification Submissions (510(k)s): http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345277.htm
- 510(k) Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Regulation & Policy References

- Food and Drug Administration Safety and Innovation Act (FDASIA): http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm20027187.htm
- Medical Device User Fee Amendments 2012 (MDUFA III): http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/default.htm
- Fact Sheet: Medical Device User Fee Amendments of 2012: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm313695.htm
- CDRH Plan of Action for 510(k) and Science Reports: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm239448.htm
- Plan of Action for Implementation of 510(k) and Science Recommendations: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM239450.pdf
- Medical Device User Fee Rates for Fiscal Year 2014: http://www.gpo.gov/fdsys/pkg/FR-2013-08-02/pdf/2013-18623.pdf

Additional Industry Resources

- **CDRH Learn**
  - Modules include various premarket and post-market information
  - Available 24/7
  - Certificate generated per topic upon passing post-tests, if available
  - http://www.fda.gov/cdrh/cdrhlearn/

- **Division of Small Manufacturers, International, and Consumer Assistance (DSMICA)**
  - 1-800-638-2041 or 301-796-7100
  - dsmica@fda.hhs.gov

Discussion